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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEPHEN GRIFFIN and GREGORY E. MIRIGIAN

Appeal 2009-003904
Application 10/729,742
Technology Center 3700

Decided:[1] July 31, 2009

Before DONALD E. ADAMS, LORA M. GREEN, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] The two-month time period for filing an appeal or commencing a civil action, as provided for in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

This is a decision on the Patent Applicants' appeal from the Patent Examiner's rejection of claims 1-9 and 11-21. Jurisdiction for this appeal is under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

The claims are directed to a catheter with an elongate shaft and a removable support means (e.g., a support rib) (claim 1), and additionally, an anchoring means (e.g., a support track) (claim 9).

Claims 1-9 and 11-21 are pending and appealed. The Examiner rejected the claims as follows:

• Claims 1-7, 9, 14, 15, 18, and 21 under 35 U.S.C. § 102(e) as anticipated by Furnish (US 6,873,868 B2, issued Mar. 29, 2005) (Ans. 3);

• Claims 11-13, 19, and 20 under 35 U.S.C. § 103(a) as obvious in view of Furnish and Rammler (US 5,327,891, issued Jul. 12, 1994) (Ans. 5 & 7); and

• Claims 16 and 17 under 35 U.S.C. § 103(a) as obvious in view of Furnish and MacDonald et al (US 6,210,396 B1, issued Apr. 3, 2001) (Ans. 6).

Claims 1, 2, 3, 9, 11, 16, and 19 are representative and read as follows:

1. A catheter comprising:
an elongate shaft having a proximal region, a distal region, and an exterior surface extending therebetween; and
removable support means for providing column support to the elongate shaft, the removable support means disposed over at least a portion of the exterior surface of the elongate shaft.

2. The catheter of claim 1, further comprising anchoring means for securing the removable support means, the anchoring means disposed on a portion of the exterior surface of the elongate shaft.

3. The catheter of claim 2, wherein the anchoring means have a cross-sectional profile configured to permit the removable support means to move axially with respect to the elongate shaft while limiting relative radial movement.

9. A modular guide catheter, comprising:

an elongate shaft having a proximal region, a distal region and a lumen extending therebetween, the elongate shaft having an external surface;

a plurality of support tracks disposed on the external surface of the elongate shaft, the support tracks axially aligned with the elongate shaft; and

a plurality of support ribs that are configured to be removably disposed over at least a portion of the plurality of support tracks,

wherein each of the support tracks have a cross-section profile configured to permit each of the support ribs to move axially with respect to each support track while limiting relative radial movement.

11. The modular guide catheter of claim 9, wherein the cross-section profile comprises an ovoid cross-section having a minor dimension perpendicular to the exterior surface of the elongate surface and a major dimension perpendicular to the minor dimension.

16. The modular guide catheter of claim 9, wherein the plurality of support tracks are heat bonded to the exterior surface of the elongate shaft.

19. The modular guide catheter of claim 9, wherein each of the plurality of support ribs comprises a fluorinated polyethylene polymer.

ANTICIPATION BY FURNISH

Claims 1-7, 9, 14, 15, 18, and 21 stand rejected under 35 U.S.C. § 102(e) as anticipated by Furnish.

Statement of the Issue

The primary issue in this rejection is whether Appellants have demonstrated that the Examiner erred in finding that the signal fibers of Furnish's catheter probe apparatus provided "column support to the elongate shaft" as recited in claim 1.

Principles of Law

During patent examination proceedings, claim terms are given "the broadest reasonable meaning . . . in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. Anticipation is an issue of fact, and the question of whether a claim limitation is inherent in a prior art reference is a factual issue." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (citations omitted).

"Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, or 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products." *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977). "Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product." *Id.* Thus,

once "the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990).

Facts[2]

The Furnish patent

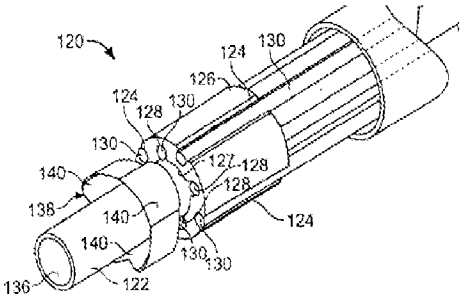
1. Furnish describes a catheter probe apparatus to analyze body tissue using an energy spectrum distributed and received by an elongated multi fiber probe introduced by a catheter. (Col. 1, ll. 50-55.)

2. The probe comprises an elongated cylindrical housing with a lumen and "an outer peripheral surface having a plurality of spaced apart, parallel, longitudinally directed alignment grooves thereon" which receive the flexible signal fibers. (Col. 1, ll. 58-66 & Col. 2, ll. 2-3.)

3. The apparatus "may" have an outermost catheter sheath, shown in Figs. 1A-B as surrounding the signal fibers. (Col. 8, ll. 12-15.)

4. "The annular housing into which the alignment grooves are fabricated mates about an elongated extrusion [housing] having a central bore" (Col. 4, ll. 1-3).

5. Figure 7, reproduced below, shows an elongated housing 122 having internal 128 and external 124 alignment grooves fabricated circumferentially around it. (Col. 9, l.65 to Col. 10, l. 3.)



[2] The numbered paragraphs are findings and conclusions of fact.

Figure 7 shows exterior alignment grooves 124, each "adjacent the external peripheral surface 126 of the housing 122" and "each carrying a signal fiber 130" (Col. 10, ll. 3-6). The signal fibers are "longitudinally displaceable" within the alignment grooves (*id.* at col. 2, ll. 48-52).

6. "The annular housing 122 into which the alignment grooves 124 and 128 are fabricated mates about the elongated extrusion 122 having a central bore 136 therethrough." (Col. 10, ll. 10-14.)

Claims 1, 2, and 3

Claim 1

7. Claim 1 is to a catheter comprising:

8. • an elongate shaft; and

9. • a removable support means "for providing column support to the elongate shaft" which is "disposed over at least a portion of the exterior surface of the elongate shaft."

10. The phrase "column support" would be understood from the Specification to refer to the strength of the catheter shaft. (Spec. 1: 7-13.) The claim does not require the support means to impart a specific degree or quantity of strength to the shaft.

Claim 2

11. Claim 2 is to the catheter of claim 1, "further comprising anchoring means for securing the removable supports means" which is "disposed on a portion of the exterior surface of the elongate shaft."

12. The Specification did not define the term "securing," but it provided examples in which the anchoring means held the support means in place

while permitting the support means to advance longitudinally over it. *See* Spec. 11:22-29, where the support ribs are the "removable support means" and the "support tracks" are the "anchoring means." The ribs can be advanced longitudinally ("slid axially") over the support track. (*Id.*)

Claim 3

13. Claim 3 is to the catheter of claim 2, where the anchoring means has "a cross-sectional profile configured to permit the removable support means to move axially with respect to the elongate shaft while limiting radial movement."

14. The term "axially" would be understood to mean movement along the shaft's longitudinal axis (F12).

15. The phrase "radial movement" would be understood to mean movement which is perpendicular to the longitudinal axis of the shaft.

Comparison between Furnish and claims 1, 2, and 3

16. Furnish's elongated housing 122 is an elongated shaft (F5-6) and therefore meets the limitation of claim 1 of an "elongate shaft" (Ans. 4).

17. Furnish's signal carrying fibers 130, arranged longitudinally on the surface of the elongated housing 122 (F2 & 5), would have been reasonably believed to provide a degree of "column support" or strength to the housing 122 as required by claim 1 because of their added material and longitudinal disposition over the length of the housing.

18. The signal carrying fibers are also "disposed over . . . the exterior surface of the" housing 122 as in claim 1.

19. Thus, the signal carrying fibers meet all the limitations of the claimed removable support means. (Ans. 4.)

20. The longitudinal alignment grooves 128 hold the signal carry fibers ("support means") (F2 & 5) and therefore act as their "anchoring means" as recited in claim 2. (Ans. 4.)

21. Although Furnish does not describe the alignment grooves as "securing the removable support means" as recited in claim 2, the alignment grooves hold the fibers in place along the circumference of the shaft, while permitting axial movement, and thus perform the same function as disclosed for the claimed anchoring means (F12).

22. The alignment grooves permit the fibers to move axially (F5; "longitudinally displaceable") as in claim 3 (F13-14; Ans. 4).

23. Furnish does not explicitly state that the radial movement of the fibers are restricted, persons of ordinary skill in the art would have reasonably believed that such limitation of claim 3 is met because otherwise the fibers would fall out when used in a subject's body and when displaced longitudinally along the groove.

Analysis

Appellants contend that the Examiner erred in finding that the Furnish signal fiber 130 is equivalent to the claimed "removable support means for providing column support to the elongate shaft." Appellants argue:

> Furnish describes signal fiber 130 as being a signal fiber for delivering or receiving beams of light. Furnish neither describes nor suggests, to one of ordinary skill in the art, that signal fiber 130 does or is capable of performing as a removable support means for providing column support to the elongate shaft.

(Reply Br. 2.) Appellants also assert that the signal fiber 130 does not perform the same function as claimed in the same way with substantially the same results. (*Id.* at 3.)

It is axiomatic that the PTO has no facilities for testing whether a product disclosed in the prior art is the same as one which is claimed. *In re Best*, 562 F.2d at 1255. For this reason, the burden has been placed on the applicant for a patent to prove that a prior art produce does not "necessarily or inherently possess the characteristics" of the product which is claimed. *Id.* This burden is triggered when the Examiner comes forward with a sufficient evidence – a "sound basis" – to support his conclusion. *In re Spada*, 911 F.2d at 708.

In this case, the dispute is whether the Examiner had sound basis for believing that the signal fiber 130 of Furnish would provide "column support to the elongate shaft" as required by claim 1. The evidence relied upon by the Examiner to establish that the support means provide column support appears to be that the fibers were disclosed by Furnish as being disposed along the shaft's entire length and were indistinguishable in structure from the support means recited in the claim.

The Examiner's evidence was adequate. Neither the Specification nor the claims require the support means to have a specific structure or be made from a specific material. The claims do not recite that the support means imparts a specific degree or quantity of strength to the shaft (F10). As shown in the preferred embodiments in the Specification, the support means add extra materials to the shaft column in the form of ribs or a sheath (Spec. 9 & 11). Accordingly, it would have been reasonably believed by skilled workers that fibers along the shaft's length would provide extra material to

the shaft and would therefore serve the function of providing at least a modicum of column strength, all that would be necessary to satisfy the claim limitation.

Appellants argue that the "mere addition of material does not imply that column support is increased. For example, the mass of the shaft may remove or overshadow any stiffness that the signal fiber may provide to the catheter." (App. Br. 8.)

This argument is not persuasive. Claim 1 does not require a specific structure or a degree of column strength to be conferred by the claimed support means. The Specification does not provide further enlightenment, except to show exemplary structures such as ribs and a sheath which add material to the outside of the shaft. (Spec. 8-11.) Accordingly, based on the evidence, the Examiner had a reasonable basis to believe that a fiber on the exterior of a shaft, the same type of structure illustrated in the Specification, would have provided at least some support strength to the shaft. Appellants have provided no persuasive evidence that the Examiner's position was flawed.

As to claim 2, Appellants contend that the alignment groove does not meet the functional requirements of an "anchoring means for securing the removable support means" because the grooves do not retain the signal fibers. (App. Br. 9.) They state: "The catheter grooves, which have parallel sides as can be seen in Figure 1A, are unable by themselves to secure the signal fibers." (*Id.*)

Although Furnish does not describe the alignment grooves as "securing the removable support means" as recited in claim 1, the alignment grooves hold the fibers in place along the circumference of the shaft, while

permitting axial movement, and thus perform the same function as disclosed for the claimed anchoring means (F12 & 21).

Appellants appear to have read the claim narrowly, requiring "securing" to mean that the grooves retain the fiber by themselves. However, Appellants have not provided evidence that the claim should be interpreted so narrowly nor that the Furnish alignment grooves do not, in fact, perform the stated function.

For claim 3, Appellants argue the "alignment grooves are unable to prevent the radial movement outwards of the signal fibers." (App. Br. 10.)

Although Furnish does not explicitly state that the radial movement of the fibers are restricted, persons of ordinary skill in the art would have reasonably believed that such limitation of claim 3 is met because otherwise the fibers would fall out when used in a subject's body and when displaced longitudinally along the groove (F23). Appellants have not provided any factual evidence that the Examiner's conclusion that the alignment grooves restrict radial movement. While several of the embodiments are shown with sheaths, Furnish does not appear to require that a sheath be present (*see* F3).

Claim 9

Claim 9 is to a guide catheter with an elongate shaft, support tracks, and support ribs. The Examiner rejected the claim on the same basis as claim 1.

Appellants argue, as they did for claim 1, that Furnish does not disclose that the support tracks are "configured to permit each of the support ribs to move axially with respect to each support track while limiting relative radial movement." (App. Br. 10.) We have addressed the argument

regarding "radial movement" of the support means for claim 3. The support ribs in claim 9 serve the same purpose as the support means of claims 1 and 3, and are not further distinguished either structurally or functionally from Furnish's signal fibers. Therefore, the argument is not persuasive for same reasons discussed for claims 1 and 3.

Appellants also state that Claim 9 recites "a plurality of support ribs that are configured to be removably disposed over at least a portion of the plurality of support tracks." Appellants contend that they "do not believe that a signal fiber extending within an alignment groove qualifies as a support rib that is disposed over at least a portion of a support track." (App. Br. 11.)

This argument is not persuasive. The signal fibers are shown in Furnish's Figure 7 (F5) as being on top and above of the alignment grooves and thus are "over" the groove as required by the claim.

Summary

The rejection of claims 1-3 and 9 is affirmed. Claims 4-7, 14, 15, 18, and 21 were not separately argued and therefore fall with claims 1-3. 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS OVER FURNISH AND RAMMLER

Claims 11-13, 19, and 20 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Furnish and Rammler.

Facts

24. Rammler describes a catheter with support tracks ("vanes") having various cross-sectional shapes and with rounded edges to minimize contact and abrasive injury. (Col. 3, ll. 35-48.) Figure 4 should an ovoid shaped vane. (Rammler, Fig. 4; Ans. 6.)

Analysis

Claims 11-13

The Examiner found that Rammler described a support tracks with an ovoid cross-section that met the limitations of claim 6. (Ans. 6; F24.) The Examiner concluded that it "would have been obvious . . . to modify the catheter as taught by Furnish, with the catheter as taught by Rammler for the purpose of configuring the geometry of a catheter support track for increased patient safety by structuring the catheter in a manner conducive to traversing bodily vasculature." (Ans. 6.)

Appellants contend:

> [T]hese cross sections, which have four sharp corners, are not ovoid. Moreover, the elements 82 and 94 of Rammler, as can be seen in Figure 4, do not limit relative radial movement between, for example, element 82 and element 86. Element 82 is small enough that it can move in and out of the groove in element 86.

(App. Br. 12.)

Appellants' have not provided sufficient evidence that the Examiner erred. First, the vane 82 in Rammler's Figure 4 is ovoid shaped as is the groove 84 into which it fits. Secondly, Rammler disclosed that the vanes can be of any cross-sectional shape or size, and specifically refers to rounding the edges (F24). Consequently, it would have been within the

level of ordinary skill in the art to produce a support means with rounded shapes to minimize contact and abrasive injury (F24) of any shape.

The rejection of claim 11 is affirmed. Claims 12 and 13 were not argued separately and therefore fall with claim 11. 37 C.F.R. § 41.37(c)(1)(vii).

Claims 19 and 20

Claims 19 and 20 are to the catheter of claim 9 where the support ribs comprise a fluorinated polyethylene polymer.

The Examiner found that Rammler described a catheter with support ribs comprising the claimed polymer and that it would have been obvious to have used it in Furnish's catheter "for the purpose of configuring the material properties of a catheter support for increased patient safety by structuring the catheter in a manner conducive to traversing bodily vasculature." (Ans. 7.)

> Appellants contend that the Examiner erred because
>
> the signal fibers of Furnish, which the Examiner has held anticipates the claimed support ribs, must transmit energy and specifically light energy from one end to the other. If the substituted material does not effectively transmit light energy, the proposed modification would make the apparatus unsuitable for its intended use. Polytetrafluoroethylene is generally opaque, which suggests that it and other fluorinated polyethers would be unsuitable for use as the signal fibers of Furnish.

(App. Br. 13.)

The Examiner did not provide adequate evidence to establish prima facie obviousness. The Examiner relied upon Furnish's teaching of signal fibers to meet the claimed limitation of support ribs. The fibers are to distribute and receive energy (F1). The Examiner has not provided any

evidence that polytetrafluoroethylene ("fluorinated polyethylene polymer") would perform this function. Consequently, we are compelled to reverse the rejection of claims 19 and 20.

OBVIOUSNESS OVER FURNISH AND MACDONALD

Claims 16 and 17 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Furnish and MacDonald (Ans. 6).

Claim 16 is to the catheter of claim 9, where the "plurality of support tracks are heat bonded to the exterior surface of the elongate shaft." Claim 17 is to the catheter of claim 9 where the "tracks are adhesively secured to the exterior surface of the elongate shaft."

The Examiner found that the difference between Furnish and claims 16 and 17 is that Furnish did not describe attaching the support tracks to the catheter with heat bond or adhesive. (Ans. 6 & 11.) However, the Examiner found that MacDonald taught attaching catheter portions with heat or adhesives and that it would have been obvious to have employed McDonald's method "for the purpose [of] configuring the material properties of a catheter support for increased patient safety." (Ans. 6-7.)

Appellants contend that the Examiner erred because one "cannot attach grooves to a catheter by heat bonding or adhesives because grooves are formed by removing material (or not applying material originally) and are not formed by adding material." (App. Br. 12-13.)

Appellants have not provided sufficient evidence that the Examiner erred. Furnish explicitly teaches that its alignment grooves – the support tracks of claim 9 – "mate" with the elongated housing (F4 & 6). As shown in Figure 7 reproduced in Fact 5, the alignment grooves appear to be a

separate element that is mated or attached to the elongate shaft 122. Therefore, Appellants statement that the grooves are formed "by removing material" does not appear to be the case for all the Furnish embodiments, particularly not the catheter apparatus show in Furnish's Figure 7.

Conclusion of Law and Summary

Appellants have not demonstrated that the Examiner erred in finding that the signal fibers of Furnish's catheter probe apparatus provided "column support to the elongate shaft" as recited in claim 1.

The obviousness rejection of claims 1-9, 11-18, and 21 is affirmed.

Appellants have demonstrated that the Examiner did not provide sufficient evidence that the subject of claims 19 and 20 would have been obvious to persons of ordinary skill in the art. The obviousness rejection of claims 19 and 20 is reversed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

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